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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/517,383	06/27/2005	Ulrik Darling Larsen	ALB.018	5689

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EXAMINER	
FRITCHMAN, REBECCA M	

ART UNIT	PAPER NUMBER
4112	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/517,383	LARSEN ET AL.	
	Examiner	Art Unit	
	REBECCA FRITCHMAN	4112	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 June 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 June 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :12/10/2004, 02/16/2005, 04/18/2008.

Detailed Action
Summary

1. This is the initial Office action based on the 10/517383 application filed on 06/27/2005.

2. The Preliminary Amendment filed has been entered and fully considered.

3. Claims 22-48 are pending and have been fully considered.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

6. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 22-23, 35-37, & 40-46 are rejected under 35 U.S.C. 103(a) as being obvious over OBERHARDT in US 6521615 in view of STAVE in US 6663833.

OBERHARDT et al. teach of analyzing cells in a carrier solution using a cartridge (column 2, lines 61-65) and interrogating the cells in the imaging field with a plurality of light (Abstract). OBERHARDT et al. do no teach of chamber for storage and mixture of reagents. STAVE et al. teach of chambers for storage and mixture of reagents (column 3, lines 23-24).

With respect to Claim 22, OBERHARDT et al. teach of a cartridge (column 2, lines 61-65) which can be used by an individual with no laboratory training and that liquid flow systems have been used to analyze and count subsets of blood cells, specifically subsets of white blood cells(column 1, lines 27-32) and of a segmented stream of liquid being sent through and open bore(column 21, lines 35-36). STAVE et al. teach of a continuous liquid flow channel containing one or more reservoirs containing buffers and reagents necessary for conducting the assay and optionally mixing or incubation reservoirs for combining the sample and the reagent wherein the locations of the sample valves and reservoirs can be modified and rearranged as

needed to optimize the conditions for a wide variety of assay formats and analytes to be detected (column 3, lines 15- 29). STAVE et al. also teach of detection on a chromatographic test strip (column 8, lines 29-30) and an orifice for passage of liquid or cells between chambers (Figure 1). Also, STAVE et al. describe the liquid flow channel being composed of a first channel segment and a second channel segment in which the sample delivery means can be adjusted to align a capillary channel within the sample delivery means with the first and second liquid flow channel segments so that the segments are both in fluid communication with the capillary channel of the valve (being movably positioned) (column 6, lines 48-57). It would have been obvious to combine the inventions of OBERHARDT et al. and STAVE et al. due to the need for simple assay devices that are easily manufactured and can be used by technical and non-technical personnel (STAVE, column 2, lines 49-58).

With respect to Claim 23, STAVE et al. teach of amending materials with additives such as surfactants (column 14, lines 34-37).

With respect to Claim 35, OBERHARDT et al. teach of a cartridge (column 2, lines 61-65) which can be used by an individual with no laboratory training and that liquid flow systems have been used to analyze and count subsets of blood cells, specifically subsets of white blood cells(column 1, lines 27-32). STAVE et al. teach of a continuous liquid flow channel containing one or more reservoirs containing buffers and reagents necessary for conducting the assay and optionally mixing or incubation (collecting chamber) reservoirs for combining the sample and the reagent wherein the locations of the sample valves and reservoirs can be modified and rearranged as

needed to optimize the conditions for a wide variety of assay formats and analytes to be detected (column 3, lines 15- 29). The continuous liquid flow channel contains a second chamber and orifice in a second wall of the chamber to allow for passage of liquid between chambers (Figure 1) a second means for characterizing(different zones on the test strip) to determine where the signal occurs(column 17, lines 10-12) and also and end of test indicator(column 19, lines 15-31). STAVE et al. also teach of detection on a chromatographic test strip (column 8, lines 29-30), and of a segmented stream of liquid being sent through and open bore (column 21, lines 35-36).

With respect to Claim 36, OBERHARDT et al. teach of a cartridge (column 2, lines 61-65) which can be used by an individual with no laboratory training and that liquid flow systems have been used to analyze and count subsets of blood cells, specifically subsets of white blood cells(column 1, lines 27-32). STAVE et al. teach of a continuous liquid flow channel containing one or more reservoirs containing buffers and reagents necessary for conducting the assay and optionally mixing or incubation reservoirs for combining the sample and the reagent wherein the locations of the sample valves and reservoirs can be modified and rearranged as needed to optimize the conditions for a wide variety of assay formats and analytes to be detected (column 3, lines 15- 29). The continuous liquid flow channel contains a second chamber and orifice in a second wall of the chamber to allow for passage of liquid between chambers (Figure 1) a second means for characterizing(different zones on the test strip) to determine where the signal occurs(column 17, lines 10-12) and also and end of test

indicator(column 19, lines 15-31). STAVE et al. also teach of detection on a chromatographic test strip (column 8, lines 29-30).

With respect to Claim 37, OBERHARDT et al. teach of a cartridge (column 2, lines 61-65) which can be used by an individual with no laboratory training and that liquid flow systems have been used to analyze and count subsets of blood cells, specifically subsets of white blood cells(column 1, lines 27-32). STAVE et al. teach of a continuous liquid flow channel containing one or more reservoirs containing buffers and reagents necessary for conducting the assay and optionally mixing or incubation reservoirs for combining the sample and the reagent wherein the locations of the sample valves and reservoirs can be modified and rearranged as needed to optimize the conditions for a wide variety of assay formats and analytes to be detected (column 3, lines 15- 29). The continuous liquid flow channel contains a second chamber and orifice in a second wall of the chamber to allow for passage of liquid between chambers (Figure 1) a second means for characterizing(different zones on the test strip) to determine where the signal occurs(column 17, lines 10-12) and also and end of test indicator(column 19, lines 15-31). STAVE et al. also teach of detection on a chromatographic test strip (column 8, lines 29-30).

With respect to Claim 40, OBERHARDT et al. teach of a sensor which is situated at various points in the instrument along the slow path (column 13, lines 2-4)

With respect to Claim 41, OBERHARDT et al. teach of a sensor being a photodectector or photodiode (column 13, lines 14-17).

With respect to Claim 42, OBERHARDT et al teach of a cell capture zone (orifice which also allows for cell capture) which has approximately a 400 micron diameter which can capture more than 600 cells of a 15 micron diameter (column 15, lines 3-53). Since the size of cells are 15 microns in diameter, it would be obvious to have an orifice from 30 micrometers to 100 micrometers to allow for passage of single cells without damage as opposed to 400 micrometers which would allow for passage of many cells.

With respect to Claim 43, OBERHARDT et al teach of a cell capture zone which has approximately a 400 micron diameter which can capture more than 600 cells of a 15 micron diameter (column 15, lines 3-53). Since the size of cells is 15 microns in diameter, it would be obvious to have an orifice from 35 micrometers to 50 micrometers to allow for passage of single cells without damage as opposed to 400 micrometers which would allow for passage of many cells.

With respect to Claim 44, OBERHARDT et al teach of a cell capture zone which has approximately a 400 micron diameter which can capture more than 600 cells of a 15 micron diameter (column 15, lines 3-53). Since the size of cells is 15 microns in diameter, it would be obvious to have an orifice from 30 micrometers to 45 micrometers to allow for passage of single cells without damage as opposed to 400 micrometers which would allow for passage of many cells.

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With respect to Claim 45, OBERHARDT et al teach of a cell capture zone which has approximately a 400 micron diameter which can capture more than 600 cells of a 15 micron diameter (column 15, lines 3-53). Since the size of cells is 15 microns in

diameter, it would be obvious to have an orifice from 35 micrometers to 40 micrometers to allow for passage of single cells without damage as opposed to 400 micrometers which would allow for passage of many cells.

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With respect to Claim 46, OBERHARDT et al teach of a cell capture zone which has approximately a 400 micron diameter which can capture more than 600 cells of a 15 micron diameter (column 15, lines 3-53). Since the size of cells is 15 microns in diameter, it would be obvious to have an orifice of 40 micrometers to allow for passage of single cells without damage as opposed to 400 micrometers which would allow for passage of many cells.

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8. Claims 24-25, & 33-34 are rejected under 35 U.S.C. 103(a) as being obvious over OBERHARDT in US 6521615 in view of STAVE in US 6663833 as applied in claims 22-23, 35-37, & 40-46 in further view of LEDIS in US 5731206.

OBERHARDT et al. teach of analyzing cells in a carrier solution using a cartridge (column 2, lines 61-65) and interrogating the cells in the imaging field with a plurality of light (Abstract). STAVE et al. teach of chambers for storage and mixture of reagents (column 3, lines 23-24). OBERHARDT and STAVE do no teach of the reagent system containing saponin of quaternary ammonium salts. LEDIS et al. do teach of the reagent system containing saponin and quaternary salts. (column 7, lines 45-46, & column 3, lines 40-43).

With respect to Claim 24, LEDIS et al. teach of the reagent system containing saponin in addition to the lytic reagent (column 7, lines 45-46). It would have been obvious to combine this with the inventions of OBERHARDT and STAVE due to the fact that separation/partitioning of the cellular fraction of the sample has been attempted with chemical agents and the results have been less than totally satisfactory (column 1, lines 65-67).

With respect to Claim 25, LEDIS et al. teach of the reagent system containing quaternary ammonium salt and cyanide ions, the system being effective to stromatolyze red bloods cells in whole blood (column 3, lines 40-43).

With respect to Claim 33, LEDIS et al. teach of reducing the size of red fragments so as to prevent their interference in determination of certain leukocyte parameters by measurement of electrical opacity and/or Coulter volume (counting) (column7, lines 53-58). This would make it obvious to reduce the size of cell types other than erythrocytes.

With respect to Claim 34, LEDIS et al. teach of cell types including leukocytes, lymphocytes, monocytes, granulocytes(column 4, lines 30-35) and of reducing the size of red fragments so as to prevent their interference in determination of certain leukocyte parameters by measurement of electrical opacity and/or Coulter volume (counting)(column7, lines 53-58). This would make it obvious to reduce the size of cell types other than erythrocytes.

9. Claim 26 is rejected under 35 U.S.C. 103(a) as being obvious over OBERHARDT in US 6521615 in view of STAVE in US 6663833 as applied in claims in further view of

LEDIS in US 5731206 as applied in claims 24-25, & 33-34 in further view of SANGHA in US 5334502 .

OBERHARDT et al. teach of analyzing cells in a carrier solution using a cartridge (column 2, lines 61-65) and interrogating the cells in the imaging field with a plurality of light (Abstract). STAVE et al. teach of chambers for storage and mixture of reagents (column 3, lines 23-24). LEDIS et al. teach of the reagent system containing saponin and quaternary salts. (column 7, lines 45-46, & column 3, lines 40-43). OBERHARDT, STAVE, and LEDIS do no teach of the use of use N-1-acetamidoiminodiacetic acid as a buffer. SANGHA et al. do teach of the use of a derivative of use N-1-acetamidoiminodiacetic acid as a buffer (column 17, lines 49-51).

With respect to Claim 26, SANGHA et al. teach of the use of N-2-acteamidoiminodiacetic acid in use as a suitable buffer (column 17, lines 49-51) (This makes it obvious that the debris from the hemolyzed red blood cells will be minimized due to a more stable cellular environment, ie pH changes will not add to cellular stress on the hemolysed red blood cells. Also, since N-2-aceteamidoiminodiacetic acid is used as a suitable buffer, it would be obvious to use N-1-acetamidoiminodiacetic acid due to their similarities. It would have been obvious to combine this with the inventions of OBERHARDT and STAVE due to the fact that conveyance of physiological fluid samples to the laboratory often occurs under poor conditions which can lead to damaged fluid samples (column 2, lines 3-12).

10. Claims 27-28 are rejected under 35 U.S.C. 103(a) as being obvious over OBERHARDT in US 6521615 in view of STAVE in US 6663833 as applied in claims 22-23, 35-37, & 40-46 in further view of SANGHA in US 5334502.

OBERHARDT et al. teach of analyzing cells in a carrier solution using a cartridge (column 2, lines 61-65) and interrogating the cells in the imaging field with a plurality of light (Abstract). STAVE et al. teach of chambers for storage and mixture of reagents (column 3, lines 23-24). OBERHARDT and STAVE do no teach of the use of use N-1-acetamidoiminodiacetic acid as a buffer. SANGHA et al. do teach of the use of a serivative of use N-1-acetamidoiminodiacetic acid as a buffer (column 17, lines 49-51).

With respect to Claim 27, SANGHA et al. teach of the use of N-2-acteamidoiminodiacetic acid in use as a suitable buffer (column 17, lines 49-51) (This makes it obvious that the leukocytes will be stabilized due to a more stable cellular environment, ie pH changes will not add to cellular stress on the leukocytes during hemolysis of the red blood cells.). Also, since N-2-aceteamidoiminodiacetic acid is used as a suitable buffer, it would be obvious to use N-1-acetamidoiminodiacetic acid due to their similarities. It would have been obvious to combine this with the inventions of OBERHARDT and STAVE due to the fact that conveyance of physiological fluid samples to the laboratory often occurs under poor conditions which can lead to damaged fluid samples (column 2, lines 3-12).

With respect to Claim 28, SANGHA et al. teach of the use of N-2-acteamidoiminodiacetic acid in use as a suitable buffer (column 17, lines 49-51). Also,

since N-2-aceteamidoiminodiacetic acid is used as a suitable buffer, it would be obvious to use N-1-acetamidoiminodiacetic acid due to their similarities.

11. Claims 29, & 31 are rejected under 35 U.S.C. 103(a) as being obvious over OBERHARDT in US 6521615 in view of STAVE in US 6663833 as applied in claims 22-23, 35-37, & 40-46 and in further view of BECKER in US 5045474.

OBERHARDT et al. teach of analyzing cells in a carrier solution using a cartridge (column 2, lines 61-65) and interrogating the cells in the imaging field with a plurality of light (Abstract). STAVE et al. teach of chambers for storage and mixture of reagents (column 3, lines 23-24). OBERHARDT and STAVE do no teach of the lysing reagent containing the compounds1,2,4-Triazole, dodecyltrimethylammonium chloride or inorganic salts. BECKER et al. teach of the use of an inorganic salt (column 4, lines 66-67) and chlorihexidene diacetate, and dimethylolurea (column 5, line 5).

With respect to Claim 29, BECKER et al. teach of the using 1, 3-dimethylurea (column 4, line 65), chlorihexidene diacetate, and dimethylolurea (column 5, line 5). It would have been obvious to combine this with the inventions of OBERHARDT and STAVE due to the valuable role that leukocyte differentiation plays in the detection of diseases (column 1, lines 36-37).

With respect to Claim 31, BECKER et al. teach of an inorganic salt which is used to correct conductivity (column 4, lines 66-67). It would be obvious to incorporate this salt into the cell analysis devices of OBERHARDT and STAVE due to the valuable role

that leukocyte differentiation plays in the detection of diseases (column 1, lines 36-37)(correcting conductivity will help with differentiation).

12. Claim 30 is rejected under 35 U.S.C. 103(a) as being obvious over OBERHARDT in US 6521615 in view of STAVE in US 6663833 as applied in claims 22-23, 35-37, & 40-46 and in further view of LI in US 5882934.

OBERHARDT et al. teach of analyzing cells in a carrier solution using a cartridge (column 2, lines 61-65) and interrogating the cells in the imaging field with a plurality of light (Abstract). STAVE et al. teach of chambers for storage and mixture of reagents (column 3, lines 23-24). OBERHARDT and STAVE do no teach of the lysing reagent containing the compounds triazole or tetrazole. LI et al does teach of the lytic reagent containing triazole or tetrazole (column 10, lines 24-37).

With respect to Claim 30, LI et al. teach of the use of triazole and tetrazole in a lytic reagent which are suitable for spectrophotometric analysis (column 10, lines 24-37). It would have been obvious to combine this with the inventions of OBERHARDT and STAVE due to the fact that counting and differentiating different types of leukocytes in a blood sample provides valuable information for clinical diagnosis (column 1, lines 33-35).

13. Claim 32 is rejected under 35 U.S.C. 103(a) as being obvious over OBERHARDT in US 6521615 in view of STAVE in US 6663833 in further view of BECKER in US 5045474 as applied in claims 29 and 31and in further view of LI in US 5882934.

OBERHARDT et al. teach of analyzing cells in a carrier solution using a cartridge (column 2, lines 61-65) and interrogating the cells in the imaging field with a plurality of light (Abstract). STAVE et al. teach of chambers for storage and mixture of reagents (column 3, lines 23-24). OBERHARDT and STAVE do no teach of the lysing reagent containing the compounds1,2,4-Triazole, dodecyltrimethylammonium chloride or tetrazole. BECKER and LI teach of the use of dodecyltrimethylammonium chloride, tetradecyltrimethylammonium bromide (BECKER, column 5, lines 33-51), and triazole/tetrazole (LI, column 10, lines 24-37).

With respect to Claim 32, BECKER et al. teach of the lysing reagent which must be capable of categorizing the white cell population into three distinct subpopulations being selected from tetradecyltriammonium bromide and dodecyltrimethylammonium chloride, hexadecyltrimethyl ammonium chloride, tetradecyltrimethylammonium bromide, and mixtures thereof (column 5, line 33-51). LI et al. teach of the use of triazole and tetrazole in a lytic reagent which are suitable for spectrophotometric analysis (column 10, lines 24-37). It would have been obvious to combine this with the inventions of OBERHARDT and STAVE due to the fact that counting and differentiating different types of leukocytes in a blood sample provides valuable information for clinical diagnosis (column 1, lines 33-35).

14. Claim 38 is rejected under 35 U.S.C. 103(a) as being obvious over OBERHARDT in US 6521615 in view of STAVE in US 6663833 as applied in claims 22-23, 35-37, & 40-46 and in further view of SEYMOUR in US 5393496.

OBERHARDT et al. teach of analyzing cells in a carrier solution using a cartridge (column 2, lines 61-65) and interrogating the cells in the imaging field with a plurality of light (Abstract). STAVE et al. teach of chambers for storage and mixture of reagents (column 3, lines 23-24). OBERHARDT and STAVE do no teach of a breakable seal separating the reagent chamber from the mixing chamber. SEYMOUR et al. do teach of a breakable seal (column 18, lines 53-65).

With respect to Claim 38, SEYMOUR et al. teach of a breakable seal in a saliva sample testing device in which the seal breaks and allows the mixture of the buffering solution and the sample of saliva to flow (column 18, lines 53-65). It would have been obvious to combine this with the inventions of OBERHARDT and STAVE due to prior teachings of a sampling device in which after the specimen is obtained, the specimen collector is force through the seal into a liquid preservative (column 2, lines 10-15).

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to REBECCA FRITCHMAN whose telephone number is (571)270-5542. The examiner can normally be reached on Monday- Friday 7:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gilliam Barbara can be reached on 571-272-1330. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

R.F.

/Barbara L. Gilliam/
Supervisory Patent Examiner, Art Unit 4128